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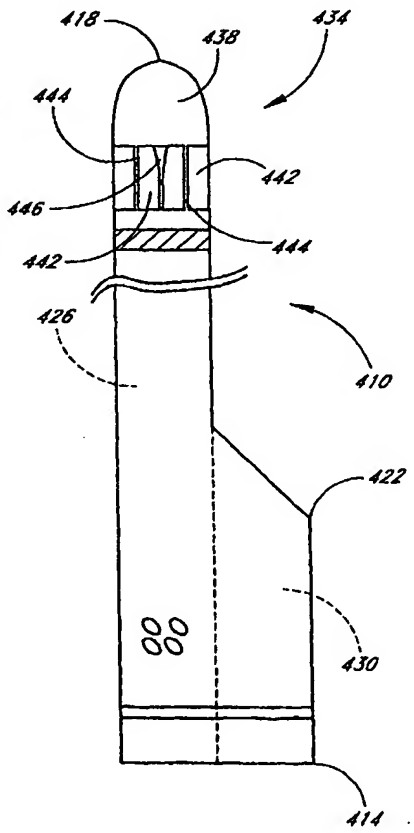

(57) Abstract: A multilumen catheter that maximizes the blood flow into and out of the patient's vasculature while also providing for passive and/or active perfusion of tissue downstream of where the catheter resides in the vasculature. The inventive catheter comprises a proximal end, a first distal and a second distal end with first and second lumens extending from the proximal end to each of these distal ends to provide for blood circulation within one blood vessel or between two different blood vessels. The second lumen, and any additional lumens so desired, may be positioned coaxially with or radially around the first lumen. Redirecting means is provided at a distal end of at least one of said lumens for directing blood in a direction generally opposite of the direction of flow through said lumen.

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A MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA

Background of the Invention

Field of the Invention

The present invention relates to a multilumen catheter and, in particular, to multilumen catheters designed to prevent ischemia in patients when the catheter is positioned within the body.

Description of the Related Art

It is often necessary to divert the flow of blood from a patient's blood vessel back to the same or a different blood vessel as part of treating a patient suffering from one or more of numerous health impairments, including cardiovascular disease, such as congestive heart failure. Although surgical cut-down procedures can achieve this, percutaneous insertion of catheters has made this procedure less invasive and therefore less traumatic to the patient. Still, insertion of a cannula into the circulatory system can cause complex, and sometimes adverse, reactions within the body.

Some of the percutaneous procedures involve removing blood from the body and subsequently returning it to the body. For example, dialysis treatment involves first removing blood from the patient's circulatory system, treating the blood outside of the body, and then returning the blood to the patient's circulatory system to perfuse the various tissues and organs. Depending on the volume of blood flow, cannulae with large carrying capacity may be necessary. By maximizing the cross-sectional area of the cannula, the volume of blood that may be removed and/or returned to the patient's vascular system via the cannula is maximized. One approach to maximize the cross-sectional area of the cannula involves using either two single lumen catheters or a multi-lumen catheter. In a recirculation application, one lumen would function to withdraw blood and one would function to return blood to the patient. One problem with using two single lumen catheters is that it subjects the patient to multiple percutaneous insertion procedures, which complicates the procedure and increases the potential for infection and other complications. Therefore, it would be desirable to have a catheter assembly which could be inserted into the patient through a single insertion site.

Multilumen catheters in various forms have been employed for this purpose. For example, multilumen catheters have been made with two, three or more lumens to serve various aspiration and infusion functions, including extracting and returning blood to vessels, taking blood samples for testing and providing medications to the patient's vascular system. Simple multilumen catheters have been made by providing two round catheters of equal or nearly equal length joined by a web, or thin strip. This approach is described in U.S. Patent No. 5,776,111 to Tesio. Other multilumen catheter designs have a unitary body with at least one septum dividing the lumens which extend from a proximal to a distal end.

While multilumen catheters require only a single puncture of the epidermis, their performance is limited in at least two ways. For one, the outer perimeter of the multilumen catheter cannot exceed the inner diameter of

the vessel into which it is inserted. Furthermore, the already limited cross-sectional area must be divided into at least two lumens, one for withdrawal and one for return. Thus the carrying capacity of each lumen is further reduced. To supply the same amount of blood, the velocity and pressure of the blood in the lumens must increase over what it would be in the vessel itself. This has the potential to cause damage to the vessel as blood comes jetting out of the return lumen. Also, it may put further stress upon blood cells, even causing hemolysis. Thus, multilumen catheters must be made as large as possible to carry enough blood at satisfactory conditions.

Where the size of a catheter approaches the interior size of a vessel, less and less blood can flow around the catheter. As a result, limited blood supply reaches tissues and organs located downstream of the catheter in the vascular system. With insufficient perfusion, the tissues downstream of the lumen insertion site suffer from ischemia and become oxygen deprived. Prolonged oxygen deprivation can lead to tissue damage, as is well known in the art. Therefore, it would be desirable to have a multilumen catheter that can maximize cross-sectional area of withdrawal and return lumens while at the same time providing for acceptable levels of blood perfusion of tissue downstream of the catheter insertion site in the vascular system. It would also be advantageous to have a multilumen catheter that can also remove blood from one peripheral vessel and return blood to a second peripheral vessel.

Summary of the Invention

Overcoming many if not all of the limitations of the prior art, the present invention comprises a multilumen catheter for directing the flow of blood to and from a patient through a single cannulation site. The catheter comprises a proximal end, a first distal end and a second distal end. The first distal end extends farther from the proximal end than the second distal end. A first lumen extends between the first distal end and the proximal end and a second lumen extends between the second distal end and the proximal end. At least one aperture, but preferably a plurality of apertures may be formed in one of the first or second lumens positioned near the proximal end so that the aperture permits active maintenance or enhancement of perfusion of blood to the patient's vasculature downstream of where the aperture resides in the vasculature when the catheter is inserted into the patient for treatment.

In an alternative embodiment, the multilumen catheter further comprises a third lumen with distal and proximal ends configured to be positioned entirely within the patient's vascular system. This third lumen is configured to permit the passive flow of blood downstream of the catheter site to maintain or enhance perfusion.

In another embodiment, the multilumen catheter also comprises means for redirecting at least a portion of the blood flow exiting a lumen of the catheter in a direction generally opposite of the direction of flow of blood in the catheter. In one embodiment, the redirecting means is a redirecting tip positioned at the distal end of one of the lumens. In this embodiment, the redirecting tip is configured to redirect at least a portion of the blood flow exiting the lumen in a direction generally opposite of the direction of flow.

In one embodiment, a connector formed in the shape of a Y ("Y-connector") is positioned at the proximal end of the multilumen catheter. One leg of the Y-connector is in fluid communication with the first lumen and the other leg of the Y-connector is in fluid communication with the second lumen.

Preferably, in an application of the present invention, an outflow conduit of a pumping system is fluidly engaged to one lumen of the multilumen catheter and an inflow conduit of the same system is fluidly engaged to the other lumen. The inflow and outflow conduits are fluidly coupled to a pump so that, when connected to the patient, the pump circulates blood from one distal end of the multilumen catheter to the other distal end, and also through at least one aperture in one of the first or second lumens positioned near the proximal end. In one application, the multilumen catheter of the present invention is incorporated into an extracardiac pumping system for supplementing blood circulation in a patient without any component thereof being connected to the patient's heart. Such a system is described in U.S. Patent Nos. 6,200,260 and 6,299,575, which are incorporated herein by reference. The system includes, in addition to the multilumen catheter, a pump configured to pump blood through the patient at subcardiac rates, an inflow conduit fluidly coupled to the pump to divert blood to the pump from a first blood vessel, and an outflow conduit fluidly coupled to the pump to direct blood from the pump to a second blood vessel.

Another embodiment of the present invention is an extracardiac pumping system for supplementing blood circulation through a patient without any component thereof being connected to the patient's heart. The extracardiac system comprises a multilumen catheter that has at least two lumens therethrough. Each lumen has a distal end configured for insertion into the patient's vasculature and a proximal end. At least two of the lumens are in fluid communication with each other at their proximal end. The extracardiac pumping system also comprises a pump secured within one of the lumens and configured to pump blood through the patient at subcardiac volumetric rates. The pump has an average flow rate that, during normal operation thereof, is substantially below that of the patient's heart when healthy. The pump can be operated to pump blood from one location in the patient's vasculature to a different location in the vasculature while the proximal end of each lumen resides outside the patient's body.

The present invention also provides a method for treating a patient using one of the multilumen catheters of the present invention. The method comprises the step of inserting the multilumen catheter described above into the patient at a single cannulation site of a first blood vessel, locating the catheter such that a first lumen may be in fluid communication with a second blood vessel and a second lumen may be in fluid communication with the first blood vessel, withdrawing blood from one of said blood vessels through one of the first or said second lumens, and delivering blood through the other of said first or second lumens so that blood is delivered upstream and downstream of the cannulation site.

Brief Description of the Drawings

These and other features and advantages of the invention will now be described with reference to the drawings, which are intended to illustrate and not to limit the invention.

Figure 1 is a schematic of one embodiment of the present invention multilumen catheter.

Figure 2 is a schematic of an alternative embodiment of the present invention multilumen catheter.

Figure 3 is a schematic of an alternative embodiment of the present invention multilumen catheter with a distal end comprising a J-tip configuration.

Figure 4 is a schematic of an alternative embodiment of the present invention multilumen catheter comprising a Y-connector.

Figure 5 is a schematic of one application of one embodiment of the multilumen catheter to a patient.

Figure 6 is an enlarged view of a portion of the proximal end of the embodiment shown in Figure 1 applied to a patient.

Figure 7 is an enlarged view of a portion of the proximal end of the embodiment shown in Figure 2 applied to a patient.

Figure 8 is a schematic of an alternative embodiment of the present invention multilumen catheter having a redirecting tip.

Figure 9 is a schematic of an alternative embodiment of the present invention multilumen catheter having coaxial lumens.

Figure 10 is a cross-sectional view of the embodiment of Figure 9.

Figure 11 is a schematic of an alternative embodiment of the present invention multilumen catheter having a second lumen and a third lumen radially housed around a first lumen.

Figure 12 is a cross-sectional view of the embodiment of Figure 11.

Figure 13 is a schematic of an extracardiac pumping system for supplementing blood circulation through a patient.

Detailed Description of the Preferred Embodiment

Turning now to the drawings provided herein, a more detailed description of the embodiments of the present invention is provided below.

With reference to Figure 1, one embodiment of the present invention comprises a multilumen catheter 10 designed to lessen ischemia that can occur when a large diameter catheter is inserted into a patient's blood vessel. The multilumen catheter preferably is of unitary construction and requires only one entry point into the patient's body. The multilumen catheter 10 comprises at least two lumens: a first lumen 12 and a second lumen 14. The first lumen 12 extends from a proximal end 16 of the multilumen catheter 10 to a first distal end 18. The second lumen 14 extends from the proximal end 16 of the multilumen catheter 10 to a second distal end 20. The lumens 12, 14 of the multilumen catheter 10 may be arranged one of many different ways. For example, the two lumens may be joined in a side-by-side manner, forming a "figure-8" when viewed from the proximal end 16. Alternately, a single cylindrical catheter housing may contain within it two or more side-by-side lumens. A cylindrical catheter housing could be formed with a diametral septum, i.e. a wall, extending

across the cylinder at a diameter. A cylindrical housing with concentrically positioned lumens is also contemplated.

The first distal end 18 may be formed with one or more distal apertures 22, although such apertures may also be located in the second distal end 20. The distal apertures 22 may be positioned close together or spaced circumferentially around the distal end. The apertures 22 serve to decrease the pressure drop across the cannula tip, thereby minimizing damage to vessel walls from jetting effects. It may also be appropriate to practice methods for directing blood flow so as to minimize damage to vessel walls from jetting effects and from the recoil effect on the catheter of blood exiting a catheter. The present invention may further comprise a tapered tip 24 at the first distal end 18, which facilitates insertion and threading of the catheter into the patient. The present invention may also further comprise a tapered tip 26 at the second distal end 20.

One preferred embodiment of the multilumen catheter further comprises a set of apertures 28 positioned on the catheter 10 near the proximal end 16. The apertures 28 are formed on at least one lumen of the catheter to provide for fluid communication between one of the lumens 12, or 14 of the multilumen catheter 10 and the blood vessel in which it resides. A radiopaque marker 30 may be positioned at the distal end 18 of the multilumen catheter 10. The multilumen catheter could further comprise markings 32 near the proximal end of the multilumen catheter which are a known distance from one or more of the distal ends. These markings 32, as well as the marker 30 can be used to accurately position the catheter when applied to the patient.

In another embodiment of the present multilumen catheter shown in Figure 2, the multilumen catheter 110 comprises a third lumen 134 extending between a proximal end 136 and a distal end 138. The lumen 134 is positioned and sized such that when the multilumen catheter 110 is applied to the patient (described below), the lumen resides entirely within the patient's body. As described above, the lumen 134 may be connected to the catheter 110 in a variety of ways. The purpose of the third lumen 134 is configured to permit the passive flow of blood downstream to the catheter to enhance perfusion. The embodiment shown in Figure 2 also may have apertures 128 disposed near the proximal end 116 of the multilumen catheter 110. As described above, this embodiment may further comprise a tapered tip 140 at the distal end of the third lumen 134 and a tapered tip 142 at the proximal end of the third lumen 134 to facilitate application of the catheter to the patient.

In one variation of the three lumen embodiment the third lumen 134 may be made of collapsible material. In the collapsed state, the third lumen 134 would conform to at least a portion of the outside surface of the multilumen catheter 110. Once applied to the patient, as described in more detail below, the lumen 134 would be expanded to the deployed state shown in Figure 2. This collapsible lumen could comprise a stone basket, or a frame similar to a stent. A stone basket is a structure that can be deployed within a patient's body and is used to capture objects. Here, the basket is used primarily to create a space between the catheter 110 and the vessel wall to permit the passive flow of blood downstream of the catheter site to enhance perfusion.

In an alternate embodiment of the multilumen catheter 210, shown in Figure 3, the first distal end 218 is formed in the shape of a J-tip. That is, the opening at the distal end 218 may be curved such that blood

exiting the lumen 212 is directed back along the multilumen catheter 210. Distal aperture(s) 222 may be formed at the bend of the J-tip so that blood also exits the lumen 212 and flows distal of the catheter 210. The "J" shape of the multi-lumen catheter tip may be formed and/or maintained by pre-loading it with a coil or with wire reinforcement, or by using a shape-memory material to create and maintain this shape. If the catheter is inserted so that the tip is straight and the "J" shape is deployed after the catheter inserted into the patient, the catheter may comprise a tapered tip at the first distal end 218, as described above.

Referring to Figure 4, yet another alternative embodiment of the present invention multilumen catheter 310 comprises a Y-connector 334 formed at the proximal end of the multilumen catheter 310. As described above, the lumens are separated in any suitable way such that fluid communication is provided between the distal end 318 of the lumen 312 of the multilumen catheter 310 and the proximal end 336 of one leg of the Y-connector 334, and fluid communication is provided between the distal end 320 of the lumen 314 of the catheter 310 and the proximal end 338 of one leg of the Y-connector 334.

Any of the multilumen catheters described herein may be made from various materials to improve their viability in long-term treatment applications. For example, it is preferred that the biocompatibility of the catheter be improved compared to uncoated catheters to prevent adverse reactions such as compliment activation and the like. To prevent such side effects, the interior lumens of the catheters can be coated with biocompatible materials. Also known in the art are anti-bacterial coatings. Such coatings may be very useful on the outer surface of the catheter. This is especially true at or about where the catheter enters the patient's skin. At such a location, the patient is vulnerable to introduction of bacteria into the body cavity. Anti-bacterial coatings can reduce the likelihood of infection and thus improve the viability of long-term treatments.

In one application, the multilumen catheter of the present invention may be integrated into a pumping system, such as the one described in more detail in U.S. Patent No. 6,200,260. Referring to Figure 5, such a system comprises the multilumen catheter 10, an inflow conduit 38, an outflow conduit 40 and a pump 42. One end of the outflow conduit 40 may be connected to the proximal end of the lumen 12, while the other end is connected to the inlet of the pump 42. One end of the inflow conduit 38 may be connected to the proximal end of the lumen 14, while the other end is connected to the outlet of the pump 42. This results in a flow from the first distal end 18 to the second distal end 20. Of course, the flow direction may be reversed using the same multilumen catheter, resulting in a flow from distal end 20 to distal end 18. In that case, the outflow conduit 40 is connected to the proximal end of lumen 14 and the inflow conduit 38 is connected to the proximal end of lumen 12. Referring to Figure 5, the present multilumen catheter 10 when incorporated into a pumping system may be applied to a patient in an arterial-arterial fashion. Where the multilumen catheter 10 is inserted into the femoral artery 44 of the patient 46. The radiopaque marker 30 which may be incorporated into the distal end 18 of the multilumen catheter is used to track the insertion of the catheter so that to catheter may be positioned at a desired site within the patient's vascular system. As mentioned above, markings 32 on the proximal end could also be used to locate the distal end or ends.

In one example, the distal end 18 may be located in the aortic arch 48. The pump draws blood from the patient's vascular system in the area near the distal end 18 and into the lumen 12. This blood is further drawn into the lumen of the conduit 40 and into the pump 42. The pump 42 then expels the blood into the lumen of the outflow conduit 38. This lumen carries the blood into the lumen 14 of the multilumen catheter 10 and back into the patient's vascular system in the area near the distal end 20. As described in greater detail below regarding Figures 6 and 7, the apertures 28 and/or the third lumen 134 provide blood flow to the patient's vasculature downstream of where the multilumen catheter resides in the vasculature to maintain or enhance perfusion of blood. The blood flow in the multilumen catheter may be reversed. In that case, blood is drawn from the patient through distal end 20 and returned to the patient through distal end 18.

Referring to Figure 6, the multilumen catheter 10 comprises features that will maintain or increase the blood flow to downstream tissue when the catheter is inserted into the patient. The apertures 28 provide for fluid communication between at least one lumen 12 or 14 and the patient's blood vessel. The apertures 28, thus, provides active perfusion of the downstream tissues.

Referring to Figure 7, the lumen 134 of the embodiment shown in Figure 2 is located entirely within the vessel when the catheter 110 is inserted into the patient. The lumen provides a pathway for blood flow to tissue downstream of the catheter so that the catheter 110 may maintain or increase the flow of blood to downstream tissue. The lumen 134, thus, provides passive perfusion. If desired, apertures may be included in one of the other two lumens to supplement passive perfusion with active perfusion.

Referring to Figure 8, yet another alternative embodiment of the present invention is a multilumen catheter 410 for directing the flow of blood through a patient through a single cannulation site. The catheter 410 comprises a proximal end 414, a first distal end 418, and a second distal end 422. The first distal end 418 extends distally farther from the proximal end 414 than does the second distal end 422. A first lumen 426 extends between the first distal end 418 and the proximal end 414. A second lumen 430 extends between the second distal end 422 and the proximal end 414. As with other embodiments, a radiopaque marker may be provided.

Means for redirecting the flow of blood out of the catheter is provided. For example, in the embodiment of Figure 8, a redirecting tip 434 is positioned at the distal end of one of the lumens, in this case first lumen 426. The redirecting tip 434 is configured to redirect at least a portion of the blood flow exiting the lumen 426 in a direction generally opposite of the direction of flow of blood in the lumen 426. One of a variety of configurations for a redirecting tip may be employed.

In the embodiment of Figure 8, the redirecting tip 434 has a closed end 438 at a distal position that is generally hemispherially shaped, although it need not be, and may more particularly have a parabolic profile. Preferably, a plurality of outlets 442 are provided in the side of the lumen 426 that has the redirecting tip 434. These outlets 442 permit blood to flow out of the lumen 426 and into the vasculature of the patient. As shown, the outlets 442 comprise rectangular windows framed by structural elements 444 that connect the

closed end 438 to the rest of the catheter 410. It should be recognized that the number and the shape of the outlets 442 can vary.

The redirecting tip 434 further comprises a flow redirecting surface 446 that defines the proximal portion of the closed end 438 and the travel path of the redirected blood. In this embodiment, a crosssection of the flow redirecting surface 446 taken through the longitudinal axis of the lumen 426 reflects two parabolic curves meeting at the longitudinal axis. The three dimensional shape of the redirecting surface 446 of this embodiment is defined by rotating one of the parabolic curves about the longitudinal axis of the lumen 426 in which the surface 446 is positioned. This is one geometrical shape that could be used to form the redirecting surface 446 to gradually redirect the flow of the blood exiting the lumen 426. Other geometrical shapes could be used as well to define the redirecting surface.

The J-tip configuration, discussed above is another means for redirecting blood in a direction generally opposite of the direction of flow of blood through the lumen 426.

Referring to Figures 9 and 10, a multilumen catheter 510 for directing the flow of blood through a patient through a single cannulation site comprises a proximal end 516 a first distal end 518 and a second distal end 520. The first distal end 518 extends distally farther from the proximal end 516 than the second distal end 520. A first lumen 522 extends between the first distal end 518 and the proximal end 516. A second lumen 524 extends between the second distal end 520 and the proximal end 516, is positioned coaxially with the first lumen 522, and has a diameter greater than the first lumen 522. A radiopaque marker may be provided if desired.

One application of the catheter 510 comprises connecting the second lumen 524 to a patient's blood vessel, preferably via an anastomosis connection after the first lumen 522, which is preferably of tubular configuration, is inserted through the same vessel. In this application, blood may be drawn through the second lumen 524 and redirected into the first lumen 522 using a circulating system such as that disclosed in U.S. Patent No. 6,200,260. In another application, the first and second lumen may be inserted in the blood vessel in a manner that results in the second lumen 524 extending into the vessel. In this application, if desired, apertures 526 may be provided to permit a more diffuse discharge of blood into the vessel from second lumen 524..

Referring to Figures 11 and 12, a multilumen catheter 610 for directing the flow of blood through a patient through a single cannulation site comprises a proximal end 616, a first distal end 618, and a second distal end 620. The first distal end 618 extends distally farther from the proximal end 616 than the second distal end 620. A first lumen 622 extends between the first distal end 618 and the proximal end 616. A second lumen 624, and if desired a third lumen 626, extend between the second distal end 620 and the proximal end 616. In one application, the third lumen 626 is in fluid communication with the second lumen 624 at a position proximal of the catheter 610, although they need not be. The second lumen 624 and third lumen 626 are positioned radially around the first lumen 622 in a housing 628 that surrounds the first lumen 622, as shown in

Figure 12. One variation of the catheter shown in Figures 11 and 12 comprises a fourth lumen in the housing 628 where, if desired, the fourth lumen may be in fluid communication with second lumen 624 and/or third lumen 626 proximal of the catheter. The fourth lumen, as well as the second lumen 624 and the third lumen 626 can be arranged in any suitable manner within the housing 628. In one embodiment, the lumens are arranged symmetrically and radially around the first lumen 622. Asymmetrical arrangements are also contemplated.

With reference to Figure 13, another embodiment of the present invention comprises an extracardiac pumping system 700 for supplementing blood circulation through a patient without any component thereof being connected to the patient's heart. The extracardiac system 700 comprises a multilumen catheter 704 and a pump 706 housed within the catheter 704.

The multilumen catheter 704 of the system 700 comprises a first lumen 708 with a proximal end 710 and a distal end 712. The catheter 704 also comprises a second lumen 716 with a proximal end 718 and a distal end 720. In other embodiments, the catheter 704 can have additional lumens, as discussed above. The distal ends 712, 720 are configured for insertion into the patient's vasculature. The two lumens 708, 716 are in fluid communication with each other at their proximal ends 710, 718. First lumen 708 is longer than second lumen 716. In other variations, the lumens 708, 716 could be of the same length.

The pump 706 is secured within one of the lumens 708, 716 and is configured to pump blood through the patient at subcardiac volumetric rates the benefits of which are discussed in U.S. Patent No. 6,200,260. The pump 706 has an average flow rate that, during normal operation thereof, is substantially below that of the patient's heart when healthy. The pump 706 may be operated to pump blood from one location in the patient's vasculature to a different location in the vasculature while the proximal end 710 of the first lumen 708 and the proximal end 718 of the second lumen 716 resides outside the patient's body. If desired, the entire system 700 may be implanted into a patient's blood vessel.

If desired, at least one aperture 724 is provided in one of the lumens, in this case lumen 708 and is positioned in the lumen distal from the proximal end 710 so that the aperture(s) 724 may reside within the patient's vasculature, close to the point of insertion. The aperture 724 can maintain or enhance perfusion of blood to the patient's vasculature downstream of where the aperture(s) 724 resides in the vasculature when inserted into the patient. As discussed above, one or more of the lumens of the catheter 704 can have a tapered tip 726. Also, at least one aperture may be positioned proximate a distal end of at least one of the lumens. In other embodiment, a third lumen could be provided that is configured similar to, and functions the same as, the third lumen 134 shown in Figure 2.

A variety of redirecting tip constructions can be employed in different embodiments of the catheter 704 of the extracardiac pumping system 700, as discussed above; for example redirecting tip 730. Also, the extracardiac pumping system 700 may be provided with a radiopaque marker 728. As discussed above, the

marker 728 can be used to position the catheter 704 of the extracardiac pumping system 700 when applied to a patient.

The invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiment is to be considered in all respects only as illustrative and not restrictive and the scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

WHAT IS CLAIMED IS:

1. A multilumen catheter for directing the flow of blood through a patient through a single cannulation site, said catheter comprising:

a catheter having a proximal end, a first distal end, and a second distal end, said first distal end extending distally farther from the proximal end than the second distal end;

a first lumen extending between said first distal end and said proximal end;

a second lumen extending between said second distal end and said proximal end; and

a redirecting device positioned at the distal end of one of the lumens and configured to redirect at least a portion of the blood flow exiting said lumen in a direction generally opposite of the direction of flow.

2. The multilumen catheter of Claim 1 wherein the redirecting device comprises a redirecting tip.

3. The multilumen catheter of Claim 1 wherein the redirecting device comprises a J-tip.

4. An extracardiac pumping system for supplementing blood circulation through a patient without any component thereof being connected to the patient's heart, the extracardiac system comprising:

a multilumen catheter having at least two lumens therethrough, each lumen having a distal end configured for insertion into the patient's vasculature and a proximal end, at least two of said lumens being in fluid communication with each other at their proximal end, wherein the multilumen catheter further comprises a redirecting device positioned at the distal end of one of the lumens and configured to re-direct at least a portion of the blood flow exiting said lumen in a direction generally opposite of the direction of flow of the blood through that lumen; and

a pump secured within one of the lumens and configured to pump blood through the patient at subcardiac volumetric rates, the pump having an average flow rate that, during normal operation thereof, is substantially below that of the patient's heart when healthy,

whereby the pump may be operated to pump blood from one location in the patient's vasculature to a different location in the vasculature while the proximal end of each lumen resides outside the patient's body.

5. The extracardiac pumping system of Claim 4 wherein the multilumen catheter further comprises at least one aperture in one of the lumens positioned in the lumen distal from the distal end so that the aperture may reside within the patient's vasculature and close to the point of insertion when the multilumen catheter is inserted into the patient so that the aperture may maintain or enhance perfusion of blood to the patient's vasculature downstream of where the aperture resides in the vasculature when the catheter is inserted into the patient for treatment.

6. The extracardiac pumping system of Claim 4 wherein the multilumen catheter further comprises an additional lumen configured to be positioned entirely within the patient's vasculature.

7. The extracardiac pumping system of Claim 4 wherein at least one lumen of the multilumen catheter is longer than at least one other lumen.

8. The extracardiac pumping system of Claim 4 wherein the distal end of at least one lumen is tapered.

9. The extracardiac pumping system of Claim 4 wherein the multilumen catheter further comprises at least one aperture positioned proximal a distal end of at least one of the lumens.

10. The extracardiac pumping system of Claim 4 wherein the multilumen catheter further comprises a radiopaque marker, wherein the radiopaque marker can be used to position the catheter when the catheter is applied to a patient

11. An extracardiac pumping system for supplementing blood circulation through a patient without any component thereof being connected to the patient's heart, the extracardiac system comprising:

a multilumen catheter having at least two lumens therethrough, each lumen having a distal end configured for insertion into the patient's vasculature and a proximal end, at least two of said lumens being in fluid communication with each other at their proximal end; and

a pump secured within one of the lumens and configured to pump blood through the patient at subcardiac volumetric rates, the pump having an average flow rate that, during normal operation thereof, is substantially below that of the patient's heart when healthy,

whereby the pump may be operated to pump blood from one location in the patient's vasculature to a different location in the vasculature while the proximal end of each lumen resides outside the patient's body.

12. The extracardiac pumping system of Claim 11 wherein the multilumen catheter further comprises at least one aperture in one of the lumens positioned in the lumen distal from the distal end so that the aperture may reside within the patient's vasculature and close to the point of insertion when the multilumen catheter is inserted into the patient so that the aperture may maintain or enhance perfusion of blood to the patient's vasculature downstream of where the aperture resides in the vasculature when the catheter is inserted into the patient for treatment.

13. The extracardiac pumping system of Claim 11 wherein the multilumen catheter further comprises an additional lumen configured to be positioned entirely within the patient's vasculature.

14. The extracardiac pumping system of Claim 11 wherein at least one lumen of the multilumen catheter is longer than at least one other lumen.

15. The extracardiac pumping system of Claim 11 wherein the distal end of at least one lumen is tapered.

16. The extracardiac pumping system of Claim 11 wherein the multilumen catheter further comprises at least one aperture positioned proximal a distal end of at least one of the lumens.

17. The extracardiac pumping system of Claim 11 wherein the multilumen catheter further comprises a radiopaque marker, wherein the radiopaque marker can be used to position the catheter when the catheter is applied to a patient

18. The extracardiac pumping system of Claim 11 wherein the multilumen catheter further comprises a redirecting tip positioned at the distal end of one of the lumens and configured to re-direct at least a portion of the blood flow exiting said lumen in a direction generally opposite of the direction of flow of the blood through that lumen.

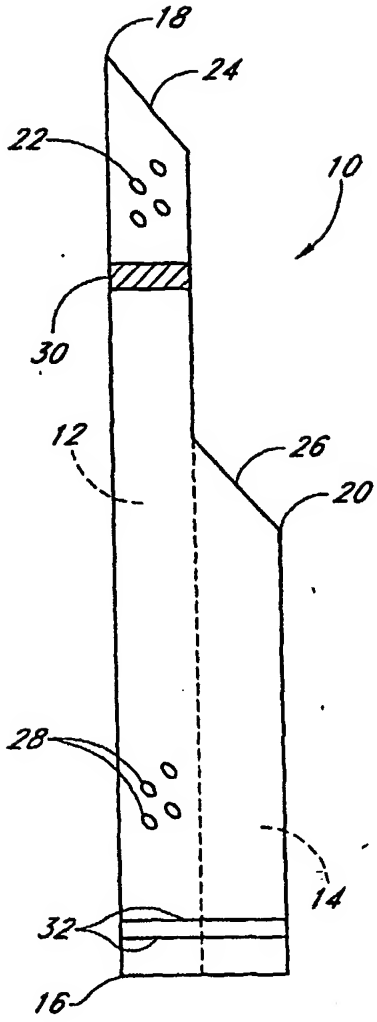
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FIG. 1

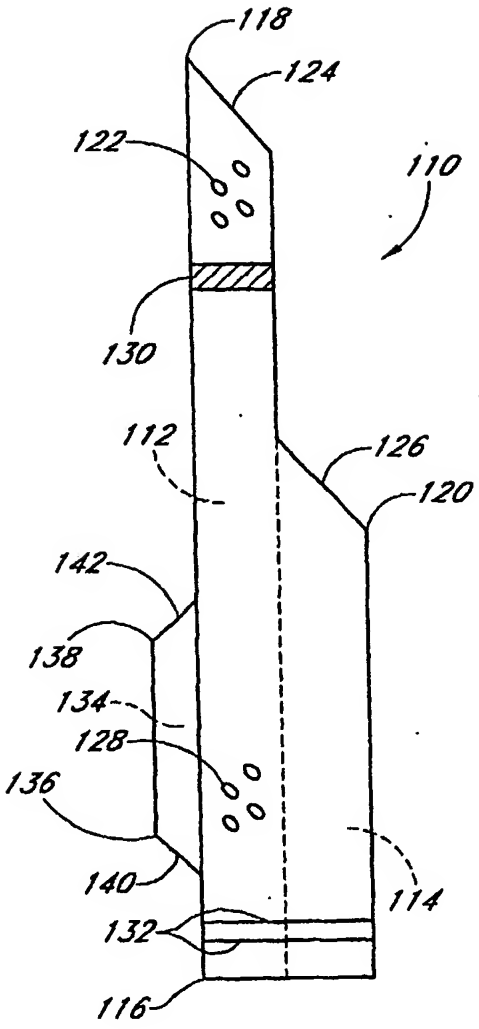
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FIG. 2

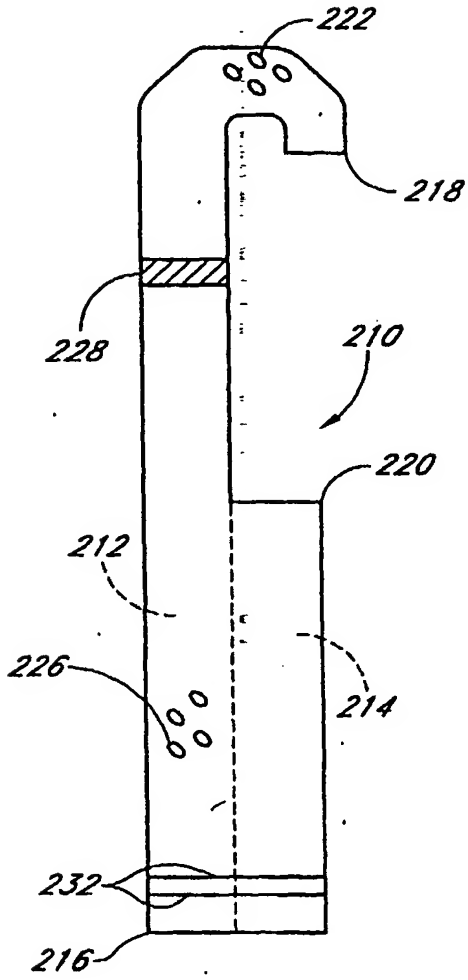
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FIG. 3

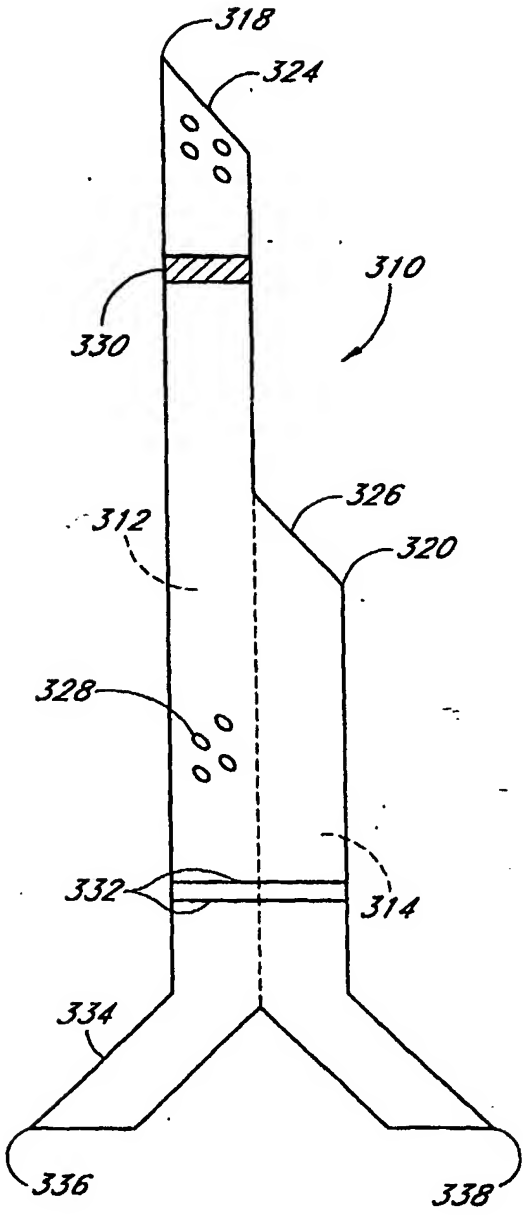
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FIG. 4

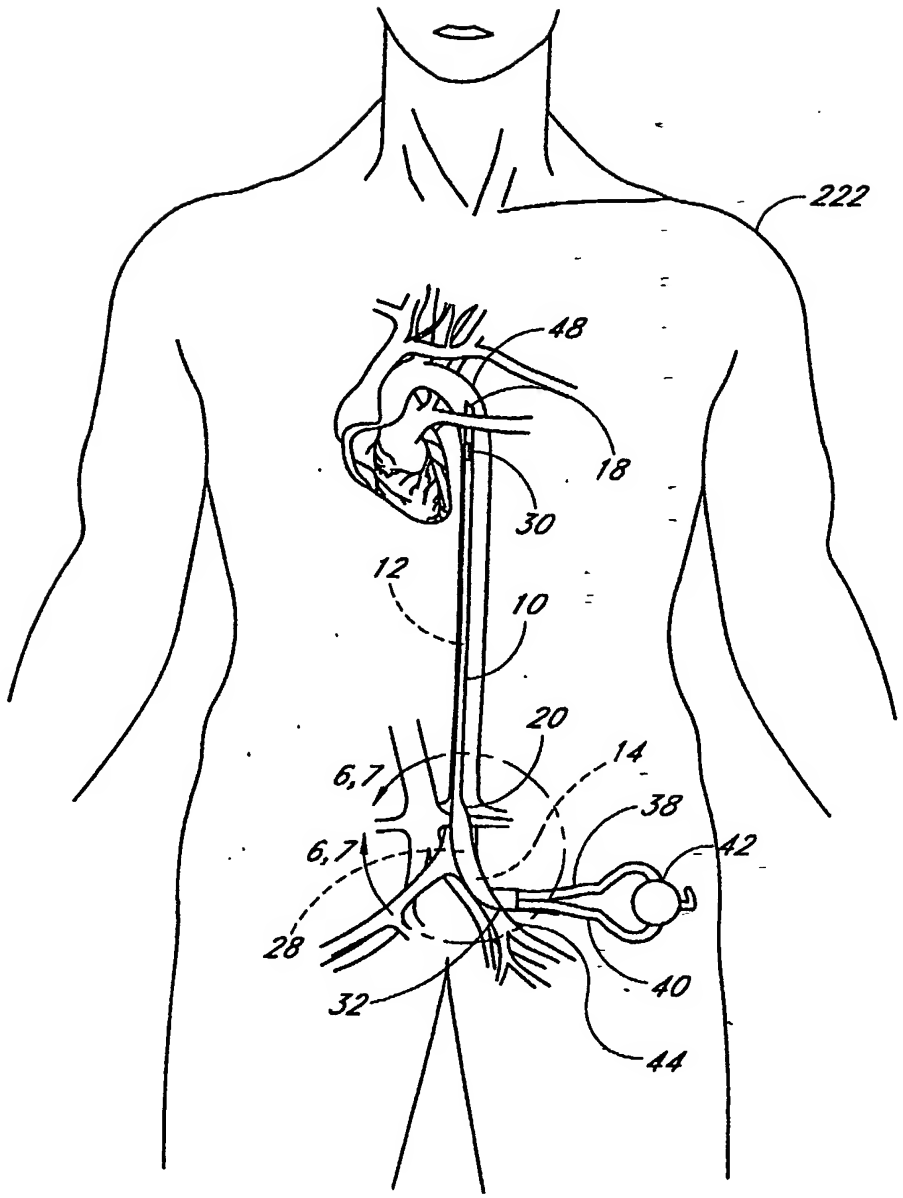

FIG. 5

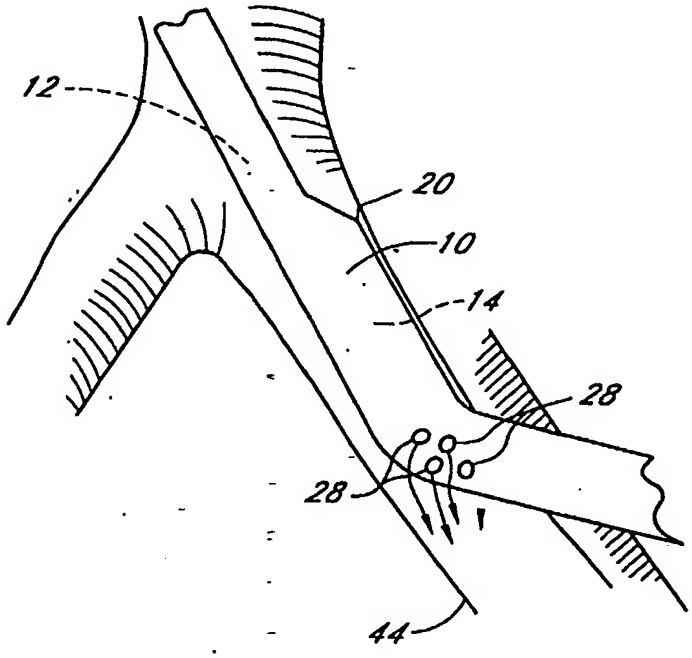

FIG. 6

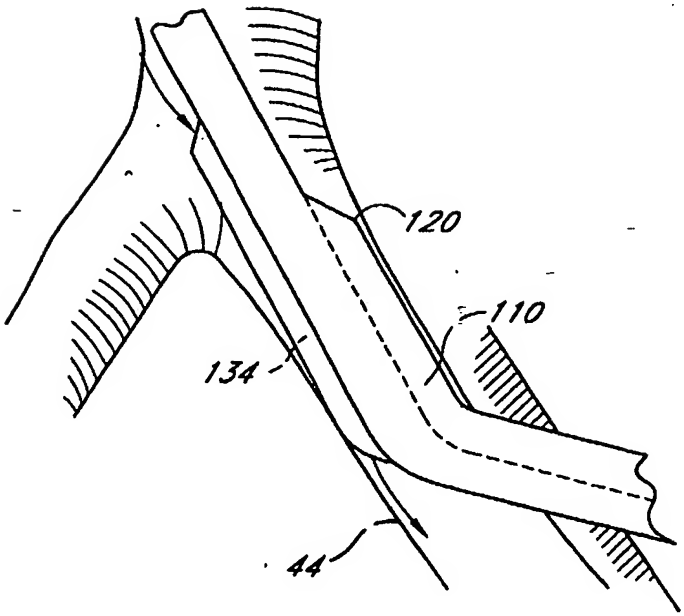

FIG. 7

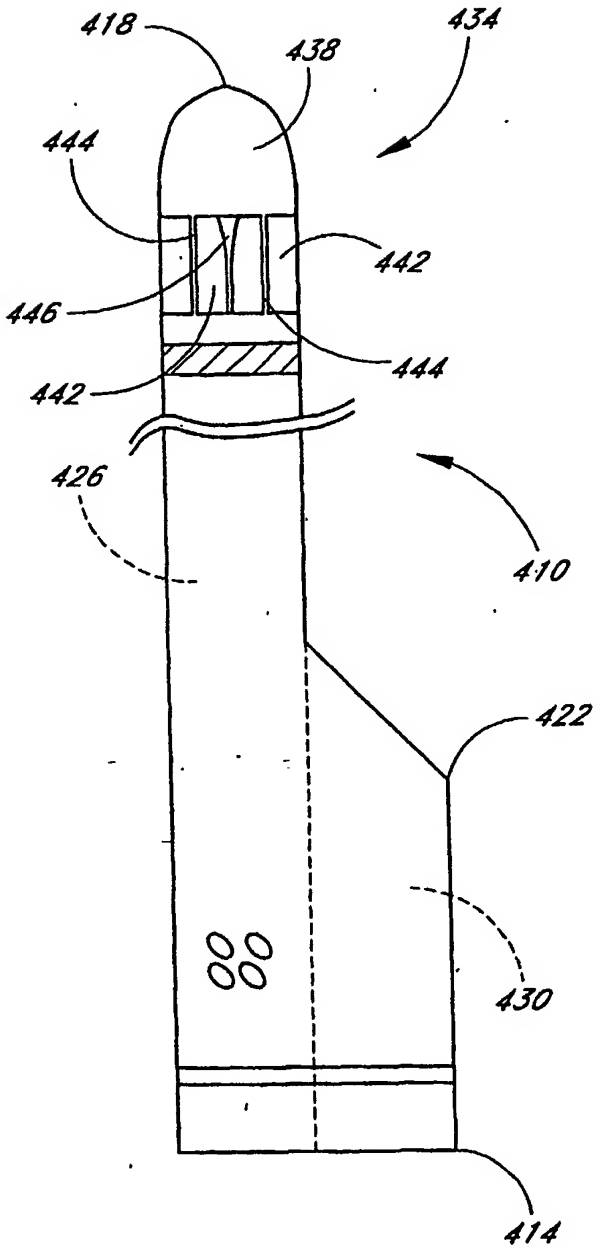

FIG. 8

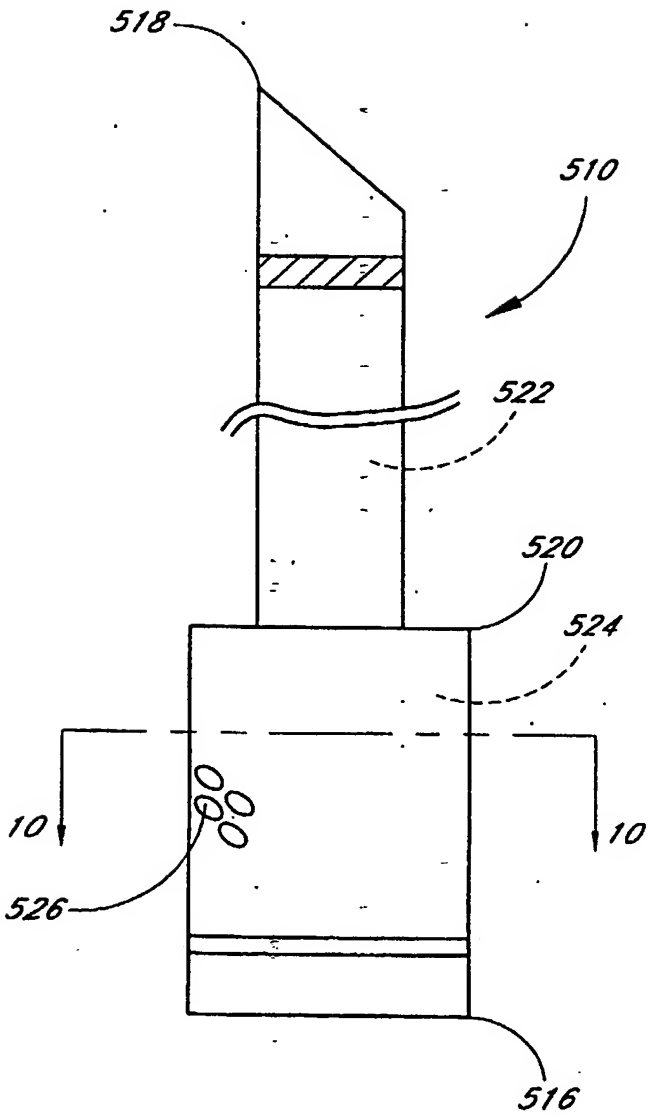

FIG. 9

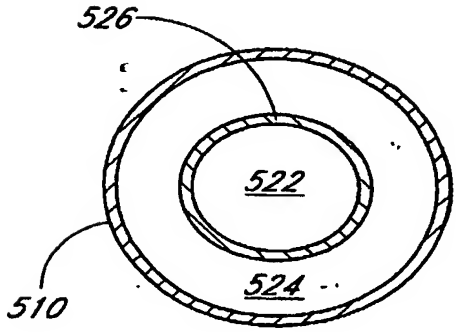

FIG. 10

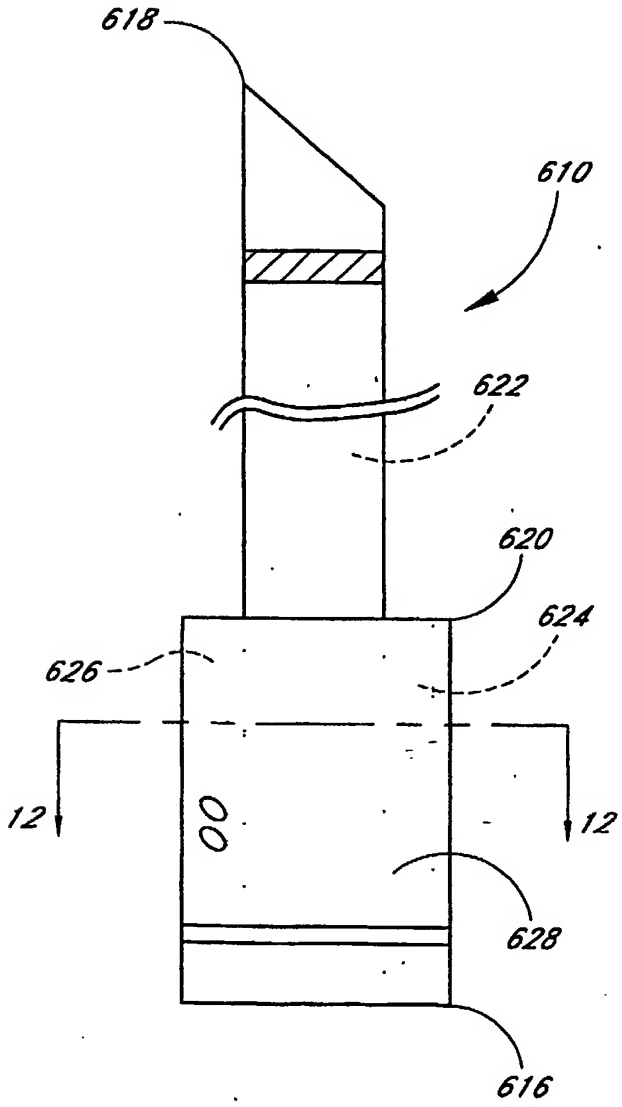

FIG. 11

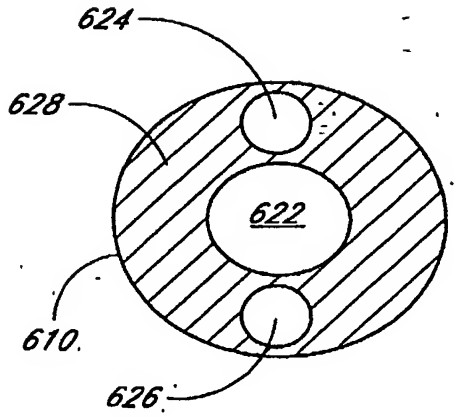

FIG. 12

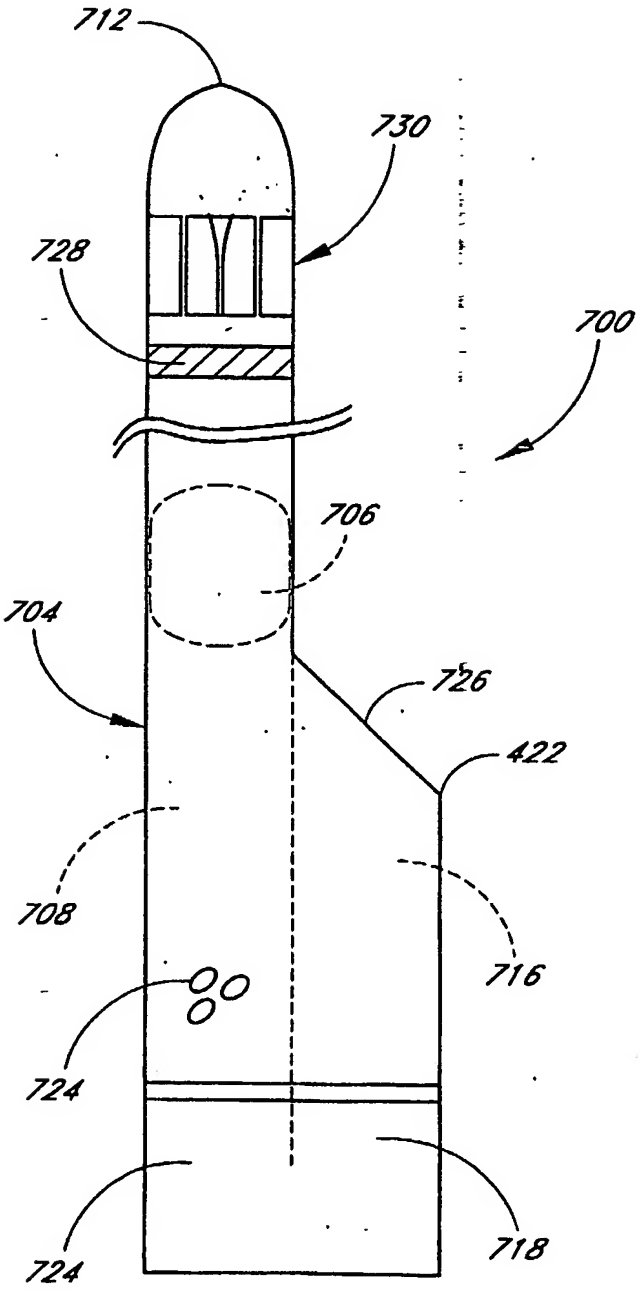

FIG. 13

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International Bureau

(43) International Publication Date
21 August 2003 (21.08.2003)

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(10) International Publication Number
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(30) Priority Data:
10/078,283 14 February 2002 (14.02.2002) US

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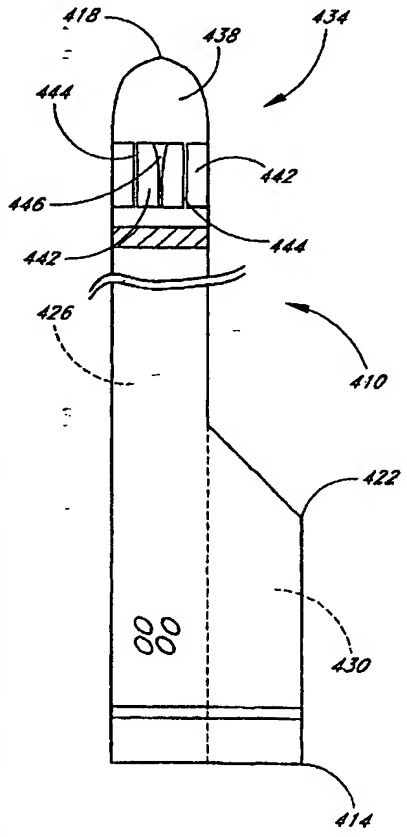
(74) Agent: DELANEY, Karoline, A.; Knobbe, Martens, Olson & Bear, LLP, 2040 Main Street, 14th Floor, Irvine, CA 92614 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ (utility model), CZ, DE (utility model), DE, DK (utility model), DK, DM, DZ, EC, EE (utility model), EE, ES, FI (utility model), FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM,

[Continued on next page]

(54) Title: A MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA



(57) Abstract: A multilumen catheter that maximizes the blood flow into and out of the patient's vasculature while also providing for passive and/or active perfusion of tissue downstream of where the catheter resides in the vasculature. The inventive catheter comprises a proximal end, a first distal and a second distal end with first and second lumens extending from the proximal end to each of these distal ends to provide for blood circulation within one blood vessel or between two different blood vessels. The second lumen, and any additional lumens so desired, may be positioned coaxially with or radially around the first lumen. Redirecting means is provided at a distal end of at least one of said lumens for directing blood in a direction generally opposite of the direction of flow through said lumen.

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PH, PL, PT, RO, RU, SC, SD, SE, SG, SK (utility model), SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) **Designated States** *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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22 January 2004

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/04401

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/00 A61M1/10 A61M1/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 807 311 A (PALESTRANT AUBREY M) 15 September 1998 (1998-09-15) claim 1; figure 1	1-3
A	EP 0 533 432 A (YAMAUCHI TEIYU ;FURUI SHIGERU (JP); CLINICAL SUPPLY KK (JP)) 24 March 1993 (1993-03-24) abstract; figure 5	1-3
A	US 5 776 111 A (TESIO FRANCO) 7 July 1998 (1998-07-07) cited in the application the whole document	1-3
X	US 4 976 270 A (PARL FRITZ F ET AL) 11 December 1990 (1990-12-11) abstract; figures 1,6-8	4-9, 11-16

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 October 2003	10. 11. 03

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Mausser, T

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/04401

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 868 703 A (BERTOLERO RAYMOND S ET AL) 9 February 1999 (1999-02-09) abstract; figures 4-8,11,12	4-9, 11-16
A	US 5 129 883 A (BLACK MICHAEL) 14 July 1992 (1992-07-14) abstract; figure 1	10,17

INTERNATIONAL SEARCH REPORT

[redacted]rnational application No.
PCT/US 03/04401

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-3

   Multilumen catheter comprising a redirecting device positioned at the distal end of one of the lumens

2. Claims: 4-18

   Pumping system comprising a multilumen catheter and a pump

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 03/04401

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
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